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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,384	ROTHMAN ET AL.	
	Examiner	Art Unit	
	CYNTHIA B. WILDER	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/23/2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/5/2009 has been entered. Claims 1-3, 16-18 have been amended. Claims 43-52 have been canceled. Claims 1-42 are pending and addressed in this Office action.

Claim Rejections - 35 USC § 103

2. The following are new grounds of rejections necessitated by Applicant's amendments. Although the claims were previously rejected as being anticipated by the same reference, Applicant's amendments have necessitated the inclusion of new grounds of rejections in the present rejection. It is noted that, to the extend that they apply to the present rejection; Applicant's arguments are addressed following the rejection.

Claim Interpretation

3. The claims as currently written require primers and probes that are broadly described based on their conserved and divergent regions as compared to another divergent region found in a *Bradyrhizobium japonicum* 16S rRNA gene. The claims do not recite any specific structures, e.g., such as nucleotide bases represented by

SEQ ID NO, that depicts the actual structure of the primer and probes of the instant invention. Moreso, the claims do not recited any specific sequences of any conserved or divergent regions of the primers and probes such that it is clear to one of ordinary skill in the art at the time of the claimed how the divergent regions are compared differ from a divergent region found in a *Bradyrhizobium japonicum* 16S rRNA gene or what actually constitutes a first, second, third, fourth and fifth divergent region of an eubacterial species. Accordingly, for the purpose of application of prior art, the examiner is interpreting the claims as not requiring hybridization to *S. aureus or B. Japonicum*. Examiner is interpreting the "conserved" and "divergent" regions as being inhereint in eubacterial species comprising 16S rRNA and represents "any sequence" found in the 16S rRNA gene of eubacterial species.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3, 7-11, 13-18, 22-26 and 28-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greisen et al (Journal of Clinical Microbiology, vol. 32, no. 2, pages 335-351, Feb. 1994) and Reischl et al (Journal of Clinical Microbiology, Vol. 38, No. 6, pages 2429-2433, June 2000). Regarding claims 1-3, 16-18 and 33-42, Greisen et al teach a method for detecting eubacterial and determining species of said eubacteria in a sample, comprising: providing universal bacterial primers that correspond to regions of the 16S rRNA gene which are highly conserved among divergent groups of eubacteria and therefore would be expected to amplify DNA from most pathogenic bacteria; providing universal bacterial probe designed from a conserved region of the 16S rRNA gene, which is located between the universal primers (see pages 340-341, sections entitled "Specificity of universal bacterial primers" and "Universal bacterial probe" and "Universal gram-positive and gram-negative probes") and performing DNA amplification (page 336, section entitled "DNA amplification") and probe hybridization (page 338). Greisen et al teach that the primers locations were chosen to be relatively specific for eubacterial genes at the 3' ends (page 341). Thus Greisen inherently meet the limitations of the claims for the conserved and divergent regions of the eubacterial species as recited in the claims. The bindings to the various divergent regions are deemed inherent by the universal primers and probes of Greisen et al.

Greisen et al do not expressly teach wherein the universal primers and universal probes are used in real-time fluorescence PCR.

Reischl et al teach a duplex LightCycler PCR assay to detection of *Staphylococcus aureus* strains and other related bacterial species (abstract). Reischl et al teach wherein the method comprises providing oligonucleotide primers and fluorescence-labeled hybridization probes, designed for amplification and sequence-specific detection of fragments within mecA and *S. aureus* specific genomic markers (page 2430, col. 2). Reischl et a teach that this duplexes approach, containing four different primers oligonucleotides and four different hybridization probes within a single capillary, revealed identical detection limits. Reischl et al teach that significant formation of primer dimers or secondary structures or other cross-reactions between oligonucleotide components, which frequently interfere with the analytical sensitivity of multiplex PCR approaches are therefore unlikely in this particular assay (bottom of page 2432, col. 2 bridging page 2432, col. 1 first five lines). Reischl et al further teach that the LightCycler device used in the method allows for ultrarapid thermal cycling and online monitoring of the amount of specific PCR products present in an amplification mixture (page 2429, col. 2, lines 14-17).

Reischl et al teach that the LightCycler HybProbe concept avoids the application of time-consuming and laborious post-amplification procedures (bottom of page 2432, col. 1). Reischl et al teach that due to its compact and reliable nature, the duplex PCR assay proved to be a valuable tool for the rapid identification of *S. aureus* isolates in the environment of a routine microbiological laboratory setting 9bottom of page 2432, col. 1

to top of col.2). Reischl et al teach that in combination with the simple boiling protocol for template DNA preparation, it can be easily integrated into the workflow of any diagnostic laboratory (page 2432, col. 2).

Therefore, one of ordinary skill in the art would have been motivated to have modified the PCR eubacterial speciation method of Greisen to encompass a real-time fluorescence PCR method as taught by Reischl instead of the traditional PCR amplification reaction based on the numerous advantages taught by Reischl et al that the LightCycler PCR assay allows for ultra-rapid thermal cycling and online monitoring of the amount of specific PCR products present in an amplification mixture, the method alleviates significant formation of primer dimers or secondary structures or other cross-reactions between oligonucleotide components and the method avoids the application of time-consuming and laborious post-amplification procedures.

Regarding claim 7-8, 10-11, 22-23 and 25-26, Greisen et al teach wherein the sample is for the detection of bacteria in blood, cerebrospinal fluid and other normally sterile body fluids, which includes urine (page 335, col. 2, last 6 lines).

Regarding claims 9 and 24, Greisen et al teach wherein the sample was treated to extract DNA from cells (see page 336, "DNA Isolation").

Regarding claims 13-15, 28-30, Reischl et al teach wherein the segment amplified is about 179 base pairs (see page 2430, col. 2).

Regarding claim 31 and 32, Greisen et al inherently teach wherein the conserved region is at least 80% identical in over 14 eubacterial species (see page 340 and 345 and Table 2).

7. Claims 4, 12, 19 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greisen et al in view of Reischl et al as previously applied above, in view of Abrams et al (6238927, effective filing date October 1998) and Iversen (6677153, effective filing date November 1999) and further in view of Buck et al (Biotechniques vol. 27, No. 3, pages 528-536, 1999). Regarding claims 4, 12, 19 and 27, Greisen et al in view of Reischl et al teach a method for detecting and determining species of eubacteria in a sample use a real time fluorescence PCR assay as previously described above.

The method of Greisen et al in view of Reischl et al differs from the instant invention in that the references do not expressly teach wherein the segment of S. aureus 16 rRNA gene comprises the nucleotides as shown in SEQ ID NO: 1 and 2.

Abrams et al teach a primer sequence that is 100% identical to the sequence of SEQ ID NO: 1 (see SEQ ID NO: 1 at col. 13 and 14), wherein said sequence is used in a method for detection of a target nucleic acid sequence.

Iversen teaches a primer sequence that is 100% identical to the sequence of SEQ ID NO: 2 (see SEQ ID NO: 25 at col. 63 and 64), wherein said sequence is used in a method for detection of a target nucleic acid sequence.

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an

established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers and probes simply represent structural homologs of the oligonucleotides taught by Abrams et al and Iversen, which are 100% derived from sequences expressly suggested by the prior art of and known in the prior art as useful for primers and probes for detecting a specific target, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

With regard to the issue of equivalence of the primers, MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

With regard to the issue of reasonable expectation of success in using such equivalents, Buck et al expressly provides a general teaching of evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18-mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95-control primers functioned, which represent 1/3 of all possible primers in the target region.

This clearly shows that every primer would have a reasonable expectation of success.

8. Claims 5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greisen et al in view of Reischl et al as previously applied above, in view of Kunsch et al

(6593114, effective filing date January 1996) and further in view of Buck et al (Biotechniques vol. 27, No. 3, pages 528-536, 1999). Regarding claims 5 and 20, Greisen et al in view of Reischl et al teach a method for detecting and determining species of eubacteria in a sample use a real time fluorescence PCR assay as previously described above.

The method of Greisen et al in view of Reischl et al differs from the instant invention in that the references do not expressly teach wherein the segment of S. aureus 16 rRNA gene comprises the nucleotides as shown in SEQ ID NO: 3.

Kunsch et al teach a sequence that is 95.7% identical to the sequence of SEQ ID NO: 3:

SEQ ID NO: 3 CACGAGCTGACGACARCCATGCA

Kunsch et al (SEQ ID NO: 5124) CACGAGCTGACGACAACCATGCA, wherein said sequence is used to detect *S. aureus* strains.

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties

and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers and probes simply represent structural homologs of the oligonucleotides taught by Kunsch et al, which is 95.7% identical to and derived from sequences expressly suggested by the prior art and known in the prior art as useful for primers and probes for detecting a specific target, such as *S. aureus*, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

With regard to the issue of equivalence of the primers, MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

With regard to the issue of reasonable expectation of success in using such equivalents, Buck et al expressly provides a general teaching of evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of

labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18-mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95-control primers functioned, which represent 1/3 of all possible primers in the target region.

This clearly shows that every primer would have a reasonable expectation of success.

9. Claims 6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greisen et al in view of Reischl et al as previously applied above, in view of Barry et al (EP 0 395 295) and further in view of Buck et al (Biotechniques vol. 27, No. 3, pages 528-536, 1999). Regarding claims 4, 12, 19 and 27, Greisen et al in view of Reischl et al teach a method for detecting and determining species of eubacteria in a sample use a real time fluorescence PCR assay as previously described above.

The method of Greisen et al in view of Reischl et al differs from the instant invention in that the references do not expressly teach wherein the segment of S. aureus 16 rRNA gene comprises the nucleotides as shown in SEQ ID NO: 4

Barry et al teach an S. aureus probe sequence that is 100% identical to the sequence of SEQ ID NO: 4 (see alignment below).

SEQ ID NO: 4 1 CCTTTGACAACTCTAGAGATAGAGCCTTCCC 31

EP 0395295 13 CCTTTGACAACTCTAGAGATAGAGCCTTCCC 43.

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers and probes simply represent structural homologs of the oligonucleotides taught by Barry et al, which is 100% derived from sequences expressly suggested by the prior art of and known in the prior art as useful for primers

and probes for detecting a specific target, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

With regard to the issue of equivalence of the primers, MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

This clearly shows that every primer would have a reasonable expectation of success.

Response to Arguments

10. Applicant traverses the rejection on the following grounds: Applicant states that the distinction between the combination f prior art and the claimed invention lies in the use of a probe to a divergent region to specifically, accurately and uniquely hybridize to bacterial DNA in a real-time PCR reaction, Applicant states that there was no way to know or predict that this sensitive discrimination would be possible using the real-time PCR reaction. Applicant states that Greisen teaches use of [probes to hybridize to a 16S rRNA gene region in a Southern blot, but not in a real-time PCR reaction.

Applicant states that Reischl teaches the use of probes to hybridize to other gene regions which are non-divergent among bacterial. Applicant states that Reischl does not teach the ability of a real-time PCR probe to discriminate among multiple similar gene regions, i.e., the divergent regions of the 16S RNA. Applicant states that even combining Reischl and Greisen's teachings, three was no way to predict that the real-time PCR reaction would permit the sensitive discrimination among various bacterial using a probe to a divergent region of 16S rRNA. Applicant states that in Example 4, three closely related Staphylococcal species wee accurately discriminated using a probe to the divergent region of rRNA. Applicant states that the example demonstrates that the discrimination was possible in the real-time PCR assay. Applicant states that none of the cited references suggested a real-time PCR reaction such as the one claimed with the one set of primers, a universal probe and one or more specific-specific divergent probes for binding to the amplicons.

11. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: The examiner acknowledges Applicant's arguments but note that the instant claims as currently written to not circumscribe with clearly what the probe and primer sequences are such that they specifically effective in discriminating among gene regions as argued by Applicant. The description recited in the claims is not informative and does not provide any limiting characteristics which would clearly depict to the ordinary artisan what applicant is making reference to. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re*

Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further , contrary to Applicant arguments, the claims do not make clear the advantages and novelty pointed out by Applicant at pages 10 and 11 of the remarks. Thus, Applicant does not provide any evidence to support the conclusions drawn in the arguments commensurate in scope with the claims as currently written.

In response to Applicant's arguments concerning the teachings of Greisen in view of Reischl et al, Applicant's attention is directed to *KSR Int'l Co. v. Teleflex Inc.* (550 U.S.____, 127 S. Ct. 1727 (2007)) where the Supreme Court determined that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103 (*KSR*, 550 U.S. at ____, 82 USPQ2d at 1397)." The Supreme Court also determined that "[t]he combination of familiar elements according to known methods is likely to be obvious when the combination does no more than yield predictable results (KSR, 550 U.S. at ___, 82 USPQ2d at 1395)."

In this case, the use of real-time PCR to analyze multiple genes or multiple regions of a gene is well known in the prior art as taught by Reischl et al and Coreless et al (citation made of record by Applicant on 4/4/2008) and thus does not present any novelty to the instant invention as the prior art provides sufficient motivation as to why one of ordinary skill in the art would be motivated to utilize real-time PCR techniques versus conventional PCR assay and/or why it would be obvious to try. Additionally, it

appears that Applicant asserts that they have successfully demonstrated using competing probes (e.g., third, fourth and fifth probes) which compete for the same stretch of DNA in a real-time PCR reaction. However, it is noted that while the specification teaches that multiple probes (e.g., a third and fourth probe) may exist and may be encompassed by the instant invention, Applicant does not successfully demonstrate their use in a real-time PCR reaction. The specification only demonstrates via example the successful use of two fluorogenic probes in the amplification reactions (see figures 1-4). Thus, this argument is not found persuasive.

Finally, in response to Applicant's arguments concerning the efficiency of their method over the cited prior art, it is once again noted that no efficiency, superiority or sensitivity has been claimed by the instant claims. MPEP states that "[A] known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994)". In this case, the claims are merely drawn to a real-time PCR reaction al taught by Reischl using the primer and probe conditions taught by the primary reference of Greisen et al. There is nothing in the claims that would suggest that the divergent regions are critical to the instant invention as Applicant provides no specific structures of the probe sequence or any specific binding activity based on probe hybridization to the divergent regions such that one of ordinary skill in the art would be drawn to the conclusions argued by Applicant. Accordingly, these arguments are not found persuasive and the prior art rejections are maintained.

Conclusion

12. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia B. Wilder/
Examiner, Art Unit 1637